Pre-operative short-course radiotherapy versus neoadjuvant radiochemotherapy in locally advanced rectal cancer (uT2N+, uT3N-/+)

25/05/2007	No longer recruiting	Prospectively registered		
		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
02/07/2007 Last Edited	Completed Condition category	Results		
		Individual participant data		
04/01/2021	Cancer	Record updated in last year		

Plain English summary of protocol

Not provided at time of registration

Study website

http://www.rrk-berlin.de/rrkweb/chirurgie/cco/forschung/forschungsschwerpunkte/Rektumstudie.pdf

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number 2004-001606-27

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Pre-operative short-course radiotherapy versus neoadjuvant radiochemotherapy in locally advanced rectal cancer (uT2N+, uT3N-/+)

Acronym

BRCT (Berlin Rectal Cancer Trial)

Study objectives

Standard treatment for locally advanced cancer of the rectum is pre-operative short-course radiotherapy or combined neoadjuvant radiochemotherapy with 5-fluorouracil (5-FU) plus post-operative chemotherapy with 5-FU. Similar long-term survival, local control and late morbidity have been reported for both these methods in non-comparative studies. In addition to other ongoing comparative trials we include a larger number of patients for adequate power and we avoid the adjuvant treatment bias by mandatory adjuvant chemotherapy in both groups. It is our hypothesis that the rate of local recurrence after five years is 12% in pre-operative short-course radiotherapy and 7% in combined radiochemotherapy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Ethics Committee of the Charité and the responsible authorities. Certified and recommended by the German Gancer Society ("Gütesiegel A") on the 29th September 2003 (ref: AA3/03/38; EudraCT-number: 2004-001606-27).

Study design

Randomised controlled multicentre trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Rectal cancer

Interventions

Group one: receiving pre-operative short-course radiotherapy (five times 5 Gy) followed by total mesorectal excision (TME) and adjuvant continous 5-FU infusion therapy for 12 weeks.

Group two: receiving neoadjuvant combined radiochemotherapy (50.4 Gy and continuous 5-FU)

followed by TME and adjuvant continous 5-FU infusion therapy for 12 weeks.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

5-fluorouracil (5-FU)

Primary outcome measure

Local recurrence, median follow up five years

Secondary outcome measures

- 1. Overall survival, median follow up five years
- 2. Disease-free survival, median follow up five years
- 3. Complete resection rate (R0 resection): measured at the date of surgery of the last patient entered
- 4. Rate of sphincter saving resection: measured at the date of surgery of the last patient entered
- 5. Acute and late toxicity (radiation related side effects), median follow up five years
- 6. Quality of life including long term bowel function, median follow up five years

Overall study start date

15/01/2004

Completion date

31/12/2009

Eligibility

Key inclusion criteria

- 1. Aged 18 years or over
- 2. Karnofsky Index 80% or better
- 3. Histological diagnosis of adeno- or mucinous carcinoma of rectum
- 4. Primary rectal cancer:
- 4.1. Maximum 12 cm above dentate line (upper limit)
- 4.2. Staged T2N+ or T3N0 or T3N+ (by endorectal ultrasound or computed tomography [CT] /magnetic resonance imaging [MRI] scan)
- 5. No evidence of metastatic disease as determined by chest X-ray and abdominal ultrasound (or CT-scan of chest and abdomen or other investigations such as positron emission tomography [PET] scan or biopsy if required)

- 6. Adequate bone marrow function with platelets more than $100 \times 10^9/l$ and neutrophils more than $2.0 \times 10^9/l$
- 8. Creatinine clearance more than 50 ml/min
- 7. Serum bilirubin less than 2.0 x upper limit of institutional normal range (ULN)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

760 patients (380 group one, 380 group two)

Key exclusion criteria

- 1. Rectal cancer other than adeno- or mucinous carcinoma
- 2. Previous or concurrent malignancies, with the exception of adequately treated basal cell carcinoma of the skin or in situ carcinoma of the cervix
- 3. Patients with locally advanced inoperable disease, such as T4-tumour
- 4. Presence of metastatic disease or recurrent rectal tumour
- 5. Any previous chemotherapy or radiotherapy, and any investigational treatment for rectal cancer
- 6. Concurrent uncontrolled medical conditions
- 7. Pregnancy or breast feeding
- 8. Clinically significant (i.e., active) cardiac disease (e.g., congestive heart failure, symptomatic coronary artery) or myocardial infarction within the last six months
- 9. Stenotic tumour which can not be passed by the colonoscope and pre-operative need of diverting stoma
- 10. Evidence of hereditary colorectal cancer (hereditary non-polyposis colorectal cancer [HNPCC] and familial adenomatous polyposis [FAP])
- 11. Medical or psychiatric conditions that compromise the patients ability to give informed consent

Date of first enrolment

15/01/2004

Date of final enrolment

31/12/2009

Locations

Countries of recruitment

Austria

Study participating centre Department of Surgery and Surgical Oncology Berlin Germany D-13125

Sponsor information

Organisation

Berlin Cancer Society (Berliner Krebsgesellschaft e.V.) (Germany)

Sponsor details

Kaiserin-Friedrich-Haus Robert-Koch-Platz 7 Berlin Germany D-10115 +49 (0)30 283 24 00 info@berliner-krebsgesellschaft.de

Sponsor type

Research organisation

Website

http://www.berlinerkrebsgesellschaft.de

ROR

https://ror.org/020yxp837

Funder(s)

Funder type

Research organisation

Funder Name

Berlin Cancer Society (Berliner Krebsgesellschaft e.V.) (Germany)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/02/2009	04/01/2021	Yes	No